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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/459,979 12/14/99 FERGUSON

M 39-196

EXAMINER

HM22/0117

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ARLINGTON VA 22201-4714

JIANG, D	
ART UNIT	PAPER NUMBER

1646
DATE MAILED:

4
01/17/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/459,979

Applicant(s)

FERGUSON, MARK WILLIAM
JAMES

Examiner

Dong Jiang

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1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 25-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/029,098.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Applicant's preliminary amendment in paper No. 2 filed on December 14, 1999 is acknowledged. Following the amendment, the original claims 1-24 are canceled and the new claims 25-32 are added, which are under consideration in the present office action.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/029098, filed on May 13, 1998.

Formal Matters

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title "Methods for promoting the healing of chronic wounds with pharmaceutical composition containing a stimulator of interferon-gamma" is suggested.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level

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of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The applicant claims "a method for promoting the healing of chronic wounds comprising the use of a stimulator of IFN- γ ". However, the specification only discloses evidence of using IFN- γ to treat acute surgical wounds by topical administration of IFN- γ . As demonstrated in the experiments, the skin wounds were created by surgical incision on day 0 and the treatment of IFN- γ was applied on day 0 prior to wounding, days 3 and 7 post wounding, and the results were collected on days 7, 14, 70 and 120 post wounding. There is no indication of "chronic wounds" in the study. A search of the prior art demonstrates accepted models related to studying chronic wound healing. For instance, Glassman et al. (*Annals of Plastic Surgery*, 16(4): 287-95, 1987. See page 288) created an animal model of chronic wound by surgical excision of skin in combination with steroid treatment to delay soft tissue healing, and Oberbaum et al. (*Harefuah*, 123(3-4): 79-82, 1992. See the abstract) reported a murine model of chronic wound by persistent mechanical irritation at the site. The wounds created in the instant case can not be considered "chronic wounds" as no reason to suggest the wounds were persistent. The applicant's experimental results demonstrated that "treatment of a site with IFN- γ actually promotes the deposition of collagen and healing with increased scarring". Based upon such observation, which clearly does not represent an experimental outcome of "chronic wounds", the specification asserts that "therefore may be used to promote the healing of chronic wounds". Clearly, it indicates that the claimed invention represents mere speculation that is not supported by either the specification or the prior art. The evidence relating to the application of IFN- γ in wound healing in certain contexts in the prior art is directly counter to the phenomena the method of the claims relies upon for efficacy, which indicates the unpredictability of the roles of IFN- γ in the healing of any given wound. As evidenced in the prior art and acknowledged in the disclosure itself, IFN- γ is known to promote the healing of certain types of wounds and to reduce the incidence of scarring. For instance, Granstain et al. (*Arch. Dermatol.*, 126: 1295-1302, 1990) reported that intralesional IFN- γ is beneficial in reducing keloidal scarring. Therefore, the skilled artisan would not reasonably expect that the claimed methods could be practiced to

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advantage to treat chronic wound or any wound. In view of the claimed subject matter, the presence of a working example corresponding to only one class of acute wounds in the specification, unpredictable nature of IFN- γ in treating wounds, and the state of the art at the time of the invention, it would require undue experimentation for the skilled artisan to practice the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25, 27-32 require the use of specific products and methods distinguished as to intended results but not set forth any steps required in the methods. It is, therefore, unclear what method applicant intends to claim. Regarding claim 25 and 27, the phrase "the use of " renders the claim indefinite because it is unclear what method step is intended. Claim 28 is confusing and indefinite because it is not clear how to stimulate IFN- γ and what processes are required for "stimulating IFN- γ ". A claim is indefinite where it merely recites a use without any active, positive steps delimiting how the use is to be practiced.

Claims 30-32 are further indefinite because it is not clear what is meant by "in conjunction with". As there is no recitation of method steps in the claims, those skilled in the art would not know how the two methods relate to each other and would not be able to make reference to "in conjunction with" in the context of another therapeutic method in claims 30- 32. Claim 31 is additionally indefinite because it is not clear what the applicant means by "with a method for promoting the healing of wounds or fibrotic disorders with reduced scarring". The specification disclosed such a method for using an inhibitor of IFN- γ , which may be a neutralizing antibody of IFN- γ . In the instant claim, it seems confusing and contradictory to use a stimulator of IFN- γ in conjunction with a neutralizing antibody of IFN- γ . Claim 32 is further indefinite and confusing because it is dependent from claim 25, which is "a method for promoting the healing or chronic wounds". The disclosure did not specify any other additional

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method for "promoting the healing of chronic wounds. It is therefore not clear how the method "for promoting the healing or chronic wounds" (claims 25) is used "in conjunction with" another method "for promoting the healing or chronic wounds" as no different methods or steps stated, and how the claim is particularly limited by the dependent claim.

Claims 26 and 29 are rejected for depending from indefinite claim 25.

Conclusion:

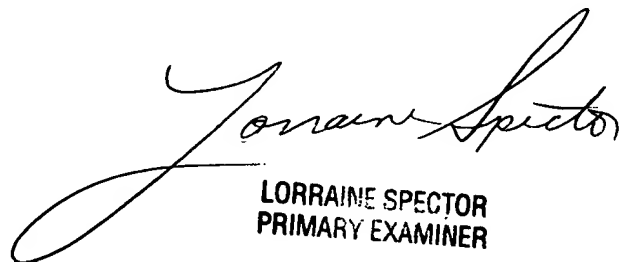
No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


LORRAINE SPECTOR
PRIMARY EXAMINER